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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,829	07/14/1999	PATRICK M SCHLIEVERT	600.347USWO	6703

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/308,829

Applicant(s)

SCHLIEVERT ET AL.

Examiner

Ja-Na A Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Amendment Entry***

1. Amendments have been entered as filed on 13 May 2002. Claims 24 and 35 have been amended. Claims 45-67 have been newly added. Claims 24-67 are under consideration in this office action.

### ***Drawings***

2. Figure 1 refers to a sequence without sequence identifying numbers being described within the figure itself or the brief description of the drawings within the specification. Therefore, appropriate correction is requested.

### ***Withdrawal of Rejections***

3. The rejection of claims 24-44 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendments.

### ***Response to Arguments***

4. Applicant's arguments filed 17 May 2002 have been fully considered but they are not persuasive.

The rejection of claims 24-44, 53 and 57-67 under 35 U.S.C. 112 first paragraph is maintained. The specification does not reasonably provide enablement for a Streptococcal pyrogenic exotoxin type C (SPE-C) mutant with three, four or five mutations at the recited positions. The specification does not enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicants' amendments to the claims do not address the enablement issues in claims 24, 35 and newly added claims 57-67. There are no examples that teach three, four or five substitutions at each of the recited positions. The specification only provides guidance to specific amino acids and does not teach any amino acid substitution may be changed without causing a detrimental effect to the SPE-C toxin to be produced. The claims recite a mutant that can be obtained by substituting one to five amino acids at positions 12, 15, 17, 35 or 38, if all five of the recited amino acid positions are substituted, the resulting mutant SPE-C could result in a mutant toxin not taught or enabled by the specification. Furthermore, the claims do not recite whether the substitution needs to be a conservative substitution. Claims 29 and 39 are drawn to a vaccine; claims 30 and 40 are drawn to a method of protection; and claims 31, 41 and 44 are drawn to a method for reducing symptoms, yet the specification does not teach using a mutant with three or more substituted positions to work in the vaccine or recited methods. There are no representative examples of endotoxins with the recited abilities. The specification does not provide substantive evidence that the claimed vaccines which teach three or more amino acid substitutions is capable of inducing protective immunity. Without a demonstration that the claimed vaccines for their intended purpose of preventing Streptococcus infections, the skilled artisan would not be able to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced by any broadly claimed mutant of SPE-C. Accordingly, one of skill in the art would be required to perform undue experimentation to use any amino acid at any location to produce a

stable SPE-C toxin. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation. Thus the rejection is maintained.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 24-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to amino acid substitutions without referring to a basic sequence which is being substituted. Therefore applicant is asked to recite the base amino acid sequence that is being used as the template for said substitutions.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines 

August 5, 2002

  
MARK NAVARRO  
PRIMARY EXAMINER